Voluntary _ Public

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Japan

Post: Tokyo

Designation of Four Substances as Food Additives

Report Categories:
Sanitary/Phytosanitary/Food Safety

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Report Highlights:
The Government of Japan has notified its intent to designate four substances (3-Methyl-2-butenal, 3-Methyl-2-butenol, 1-Penten-3-ol, and Pyrazine) as food additives. Japan notified the WTO (G/SPS/N/JPN/275) on March 25, 2011 with a closing date for comments of May 24, 2011.

General Information:

The Government of Japan (GOJ) plans to designate four substances (3-Methyl-2-butenal, 3-Methyl-2-butenol, 1-Penten-3-ol, and Pyrazine) as food additives. The GOJ notified the WTO-SPS committee of this proposed measure (G/SPS/N/JPN/275) on March 25, 2011.

http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/SPS/NJPN275.doc

The closing date for GOJ to receive comments is May 24, 2011. Comments regarding this proposal can be directed to GOJ's enquiry point at:

Standards Information Service
International Trade Division
Economic Affairs Bureau
Ministry of Foreign Affairs
2-2-1 Kasumigaseki, Chiyoda-ku
Tokyo 100-8919, Japan
Tel.: +(81) 3 5501 8344
Fax: +(81) 3 5501 8343
E-mail: enquiry@mofa.go.jp

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Background

The Ministry of Health, Labor and Welfare (MHLW) plans to newly designate four substances as authorized food additives. They are 3-Methyl-2-butenal, 3-Methyl-2-butenol, 1-Penten-3-ol, and Pyrazine.

Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only when they are designated by the Minister of MHLW. When use standards or compositional specifications are established for food additives based on Article 11 of the law, those additives are not permitted to be used or marketed unless they meet these standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council* has discussed the adequacy of designation of the three substances as food additives. The conclusion of the committee is outlined below.

Outline of conclusion

The Minister may designate 3-Methyl-2-butenal, 3-Methyl-2-butenol, 1-Penten-3-ol, and Pyrazine based on Article 10 of the Food Sanitation Law, as these food additives are unlikely to harm human health and establish compositional specifications and other necessary standards for these substances, based on Article 11 of the law (see Attachments 2-1, 2-2, 2-3, and 2-4).

Additional Information

These substances have made progress under the designated procedure for food additives, been determined safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives), and in wide use in countries other than Japan (Attachment 2-5)

Attachment 2-1

3-Methyl-2-butenal

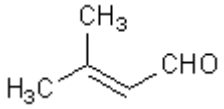
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name: 3-Methyl-2-butenal

Structural formula:



Molecular formula: C_5H_8O

Mol. Weight: 84.12

Chemical name [CAS number]: 3-Methyl-2-butenal [107-86-8]

Content: 3-Methyl-2-butenal contains not less than 97.0% of 3-methyl-2-butenal (C_5H_8O).

Description: 3-Methyl-2-butenal occurs as a colorless, transparent liquid having a characteristic odor.

Identification: Determine the infrared absorption spectrum of 3-Methyl-2-butenal, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

Purity:

(1) Refractive index n_{20D} : 1.458–1.464.

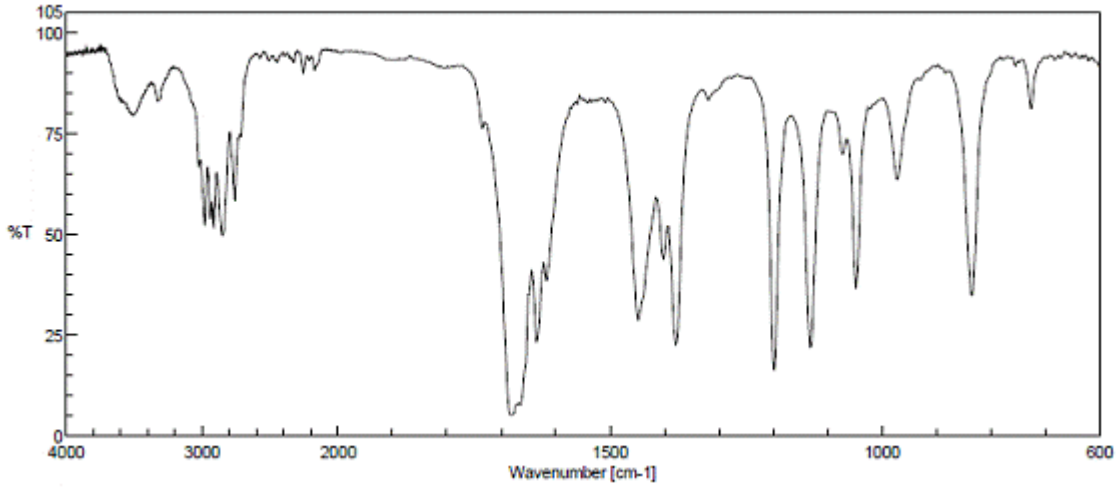
(2) Specific gravity d^{25}_{25}: 0.870–0.875.

(3) Acid value Not more than 5.0 (Flavoring Substances Tests).

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2). Use a silicate glass capillary column (0.25–0.53 mm in internal diameter and 30–60 m in length), coated with a 0.25–1 μm thick layer of polyethylene glycol.

Reference Spectrum

3-Methyl-2-butenal



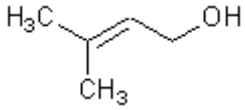
Attachment 2-2

3-Methyl-2-butenol

Standard for use
It shall not be used for purposes other than flavoring.

Compositional specifications
Substance name: 3-Methyl-2-butenol

Structural formula:



Molecular formula: $C_5H_{10}O$
Mol. Weight: 86.13
Chemical name [CAS number]: 3-Methyl-2-butenol [556-82-1]
Content: 3-Methyl-2-butenol contains not less than 98.5% of 3-methyl-2-butenol ($C_5H_{10}O$).
Description: 3-Methyl-2-butenol occurs as a colorless, transparent liquid having a characteristic odor.
Identification: Determine the infrared absorption spectrum of 3-Methyl-2-butenol, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.
Purity:
(1) Refractive index n_{20D} : 1.438–1.448.

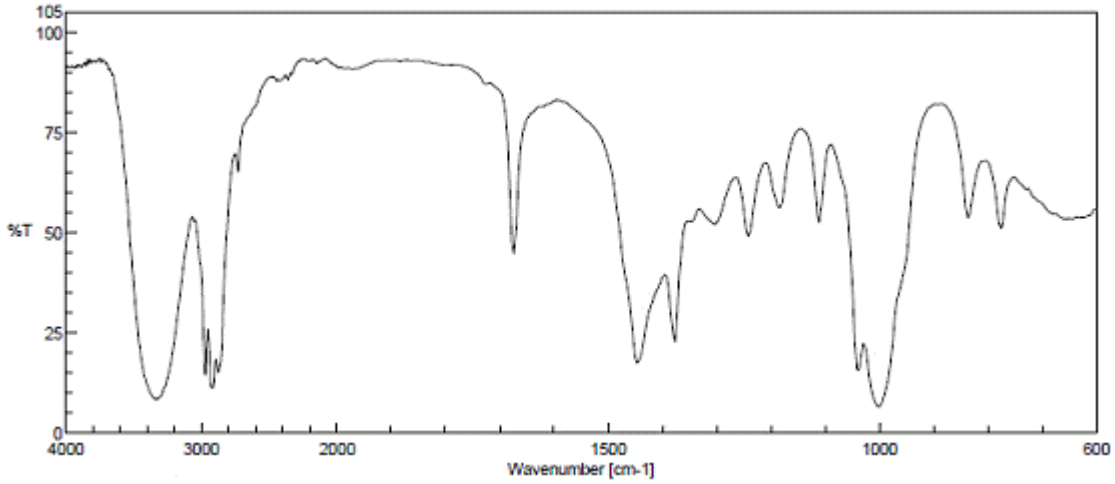
(2) Specific gravity d_{25}^{25}: 0.855–0.863.

(3) Acid value Not more than 1.0 (Flavoring Substances Tests).

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2). Use a silicate glass capillary column (0.25–0.53 mm in internal diameter and 30–60 m in length), coated with a 0.25–1 μm thick layer of polyethylene glycol.

Reference Spectrum

3-Methyl-2-butenol



Attachment 2-3

1-Penten-3-ol

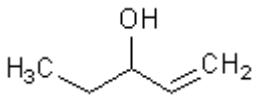
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name: 1-Penten-3-ol

Structural formula:



Molecular formula: $C_5H_{10}O$
Mol. Weight: 86.13
Chemical name [CAS number]: 1-Penten-3-ol [616-25-1]
Content: 1-Penten-3-ol contains not less than 98.0% of 1-penten-3-ol ($C_5H_{10}O$).

Description: 1-Penten-3-ol occurs as a colorless, transparent liquid having a characteristic odor.
Identification: Determine the infrared absorption spectrum of 1-Penten-3-ol, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.
Purity:

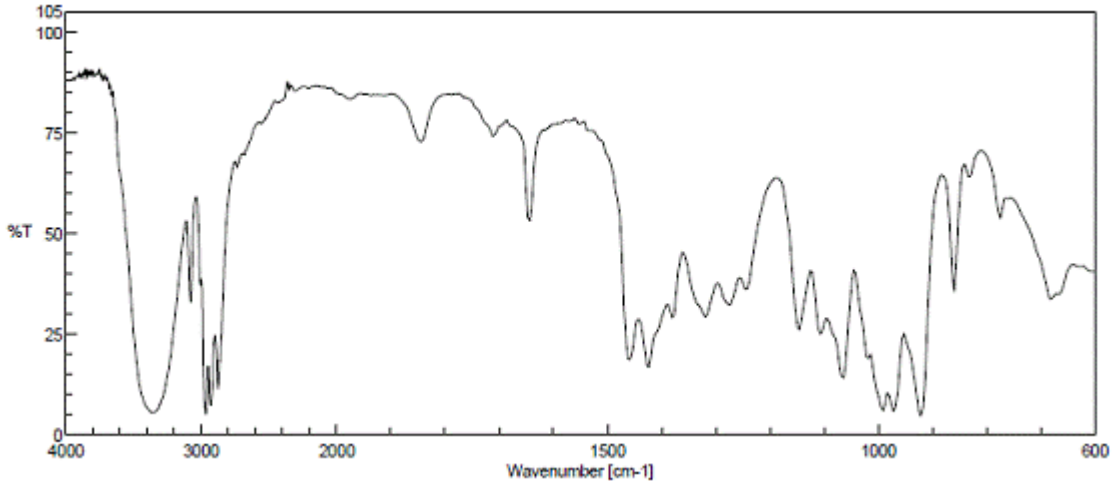
(1) Refractive index n_{D}^{20} : 1.419–1.427.

(2) Specific gravity d_{25}^{25}: 0.834–0.840.

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

Reference Spectrum

1-Penten-3-ol



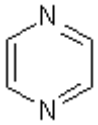
Attachment 2-4

Pyrazine

Standard for use
It shall not be used for purposes other than flavoring.

Compositional specifications
Substance name: Pyrazine

Structural formula:



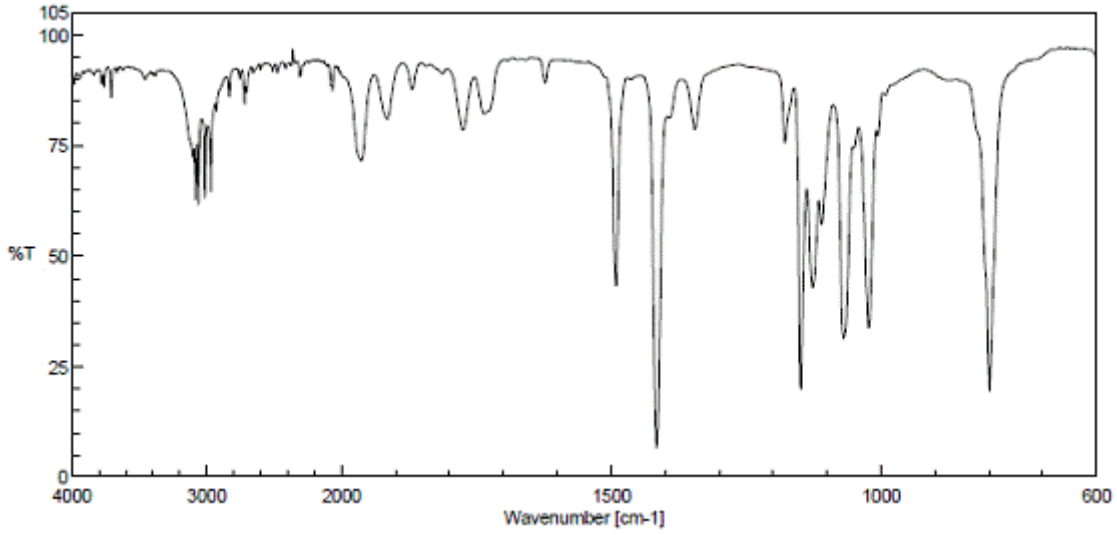
Molecular formula: $C_4H_4N_2$
Mol. Weight: 80.09
Chemical name [CAS number]: Pyrazine [290-37-9]
Content: Pyrazine contains not less than 98.0% of pyrazine ($C_4H_4N_2$).
Description: Pyrazine occurs as white to light yellow lumps, having a characteristic odor.
Identification: Hold a powdered sample of Pyrazine between two optical plates, warm to melt, and cool. Determine the infrared absorption spectrum of Pyrazine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.
Purity:

Melting point 51-55℃.

Assay: Dissolve 0.1 g of Pyrazine in 1 ml of ethanol. Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

Reference Spectrum

Pyrazine



* The English name of each committee has been changed from the Food Sanitation Committee to the Food Sanitation Council and from

the Subcommittee on Food Additives to the Committee on Food Additives, respectively.